

REMARKS

Claims 1, 2 , 4, 5, 8-11, 15, 19, and 30 are in this application.

Claims 2, 4, 5, 8, 9, 10, 15, 19, and 25 have been amended.

Claims 3, 6, 7, 12-14, 16-19, and 20-24 are cancelled.

Applicants again want to thank the Examiner for the courtesy of conducting a telephone interview with applicants' representative on April 16, 2008.

During the telephone interview the Examiner confirmed that the rejection over Skinhøj (WO 99/12524) has been withdrawn. In addition, during the interview proposed amendments to claims 2, 4, 5, 10, 15 and 25 were discussed. Support in the specification for the phrase "one or more" was also discussed.

The Examiner has withdrawn the obviousness rejection over Skinhøj and all claims are non-obvious in view of this reference .

Claim 18 has been cancelled.

Claim 19 defines that the composition for peroral administration which consists of a single unit fast release layer and a single unit extended release layer and that in the fast release layer there is nimesulide and one or more pharmaceutical excipients and that the extended release layer comprises nimesulide and release controlling material.

Claim 25 has been amended and is now an independent claim defining the controlled release pharmaceutical tablet composition as consisting of a coating, a single unit fast release layer and a single unit extended release layer.

The Examiner has rejected claims 2, 15 and 25 under 35 USC 112 second paragraph. This is respectfully traversed.

Claim 2, which further defines the composition of claim 1, has been amended to replace "which comprises" to "wherein the".

Applicants submit that this amendment has no effect on the scope of claim 2, and claim 2 is of the same scope in regard to literal infringement and infringement under the doctrine of equivalents as the previous version of claim 2.

The subject matter of claim 1 has been incorporated into claim 25. Claim 25 is now an independent claim.

Based on this amendment, it is respectfully requested that the rejection under 35 USC 112 second paragraph be withdrawn.

The Examiner has rejected claims 4, 5, 7-10, 15 and 19 under 35 USC 112 first paragraph as failing to comply with the written description requirement. This is respectfully traversed.

Claims 4, 5, 7-10, 15 and 19 have been amended to replace “or a combination thereof” with “one or more”. This is based on the originally filed claims 1-3 and 6 as well as the disclosure on page 6 of the application (see second , third and fourth paragraphs on this page). It is also understood that the sustaining materials are the release controlling materials based on the description in claim 4 and the description in the first two paragraphs of page 9 of the application.

Claim 8 has been amended and no longer includes the phrases “having affinity for gastrointestinal mucusa” or “to achieve mucoadhesion”.

Claim 9 has been amended to delete the phrase “gas generating materials”.

In regard to claim 19, applicants draw the Examiner’s attention to the second paragraph on page 10 where pharmaceutically excipients are described as being for example, fillers, bulking agents, color and stabilizers, preservers, lubricants, glidants, agents and like.

Therefore, it is respectfully requested that this rejection be withdrawn.

The Terminal Disclaimer to overcome the obviousness type double patenting rejection in regard to U.S. Patent Applications 11/545,718 and 11/978,162 is being filed with this response.

The Examiner states that claims 20-24 are no longer objected to as being dependent upon a rejected base claim. As discussed with the Examiner, claims 20-24 were cancelled previously and what in fact the Examiner was referring to is claims 26-30.

Applicant submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



JANET I. CORD
LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NEW YORK 10023
REG. NO. 33778 (212) 708-1935